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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/023,483	02/13/1998	JEFFREY A. HEROIX	2528-2	6994

7590 07/30/2002

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EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
1637	22

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/023,483	HEROUX ET AL.
	Examiner	Art Unit
	Joyce Tung	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 15 May 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-40 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input checked="" type="checkbox"/> Other: <i>Detailed Action</i> .

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### **DETAILED ACTION**

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1637.

#### ***Request for Continued Examination***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/15/2002 has been entered.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

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possession of the claimed invention. Since the newly added limitation “a threshold amount of contamination, wherein the threshold amount of contamination is equal to or less than 100 pg has no support in the specification. Specifically, “the threshold amount of contamination” has no support in the specification. Thus, it constitutes new matter.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-40 are vague and indefinite because it is unclear what is the definition regarding the language “a threshold amount of contamination” in the specification.

b. Claims 1-40 are vague and indefinite because it is unclear what is meant by “the threshold amount of contamination is equal to or less than 100pg”. Does it mean that the contamination is the target nucleic acid. Does the method is to detect the contamination DNA? Furthermore, it is unclear what is meant by “100pg”, i.e. whether it is concentration or the total amount of contamination in the sample. Clarification is required.

6. Claims 1-3, 6-12, 14-25, 28-32 and 34-37 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Hartley (5,043,272) in view of Eberle et al. (5,413,906).

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Applicants argue that there is no motivations to modify the method of Hartley's PCR with random hexamer primers into a quantitative method and there is neither teaching nor suggestion in those other cited references to use the method of Hartley to amplify low amount of substrate before a quantifying method, and subsequently to be able to determine the absolute quantity of the original amount of nucleic acid. Hartley discloses that the method might be desirable in the quantification of the amplification products (See column 8, lines 39-43). The disclosure of Hartley also indicates that very low level DNA is quantified, for example, 100pg of linear HPV 18 DNA was used (See column 10, lines 52-67 and column 11, lines 1-4) and 10 femtograms of HPV 16 DNA could be tested (See column 12, lines 57-58). Thus one of an ordinary skill in the art at the time of the instant invention would have been motivated to apply the method of Hartley combining the teachings of Eberle et al. to determine the total nucleic acid in a sample with a reasonable expectations of success because the method of Hartley is sensitive enough to be used as discussed above and the method of Eberle et al. provides a quick, simple more reliable and sensitive test (see column 2, lines 27-30).

Applicants further argue that the instant invention is able to assay complex mixture of nucleic acid, there is no reference which teaches or suggests a sensitivity of detection in the range of 100pg when amplification precedes quantification. Since the new limitations as filed are unclear whether the 100pg contamination is DNA contamination or not. Thus the limitation are not claimed. Nevertheless, Hartley did teach the sensitivity of detection in the range of 100pg

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(See column 10, lines 52-67 and column 11, lines 1-4 column 12, lines 57-58). Therefore the rejection is maintained.

7. Claims 4-5, 13, 26-27, 33 and 39-40 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Hartley (5,043,272) in view of Wu et al. (Genomics, 1989, Vol. 4, pg. 560-569) and Respess (5,599,662) with the same reasons as set forth in section 6 above.

8. Claim 38 remains rejected under 35 U.S.C. §103(a) as being unpatentable over Hartley (5,043,272) in view of Kozlowski et al. (6,096,499) with the same reasons as set forth in section 6 above.

9. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

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1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

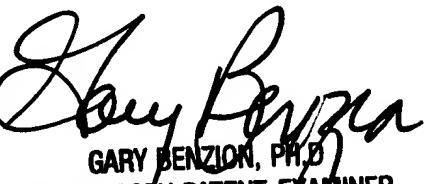
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

July 19, 2002

  
GARY BENZION, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600